

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF TEXAS

MCALLEN DIVISION

ANGELA ANDERSON; PATRICIA §  
BAILEY; JENNIFER BALDERAS; §  
BEONKA BELL; BRENDA BOSTON; §  
KATHY BOYD, as next friend of GAGE §  
WOOLSEY, minor; GENIE BRAZZEAL; §  
DEBRA CANNEY, as Representative of the §  
Estate of KEVIN BUBSEY, Deceased; §  
DEBRA CANNEY, Individually, and on §  
behalf of all Wrongful Death Beneficiaries, §  
of KEVIN BUBSEY, Deceased, including, §  
but not limited to DEBRA CANNEY; TIM §  
COSTANZA, as Representative of the §  
Estate of AMY COSTANZA, Deceased; §  
TIM COSTANZA AND JANET §  
COSTANZA, Individually, and as Wrongful §  
Death Beneficiaries of AMY COSTANZA, §  
Deceased; DOUGLAS DAILEY; RENEE §  
DAVIS, as Representative of the Estate of §  
REYNARD CRAIG BITTNER, Deceased; §  
RENEE DAVIS, Individually, and on behalf §  
of all Wrongful Death Beneficiaries of §  
REYNARD CRAIG BITTNER, Deceased, §  
including, but not limited to, RENEE §  
DAVIS; ROBERTA DENMAN; JAMES §  
DOUGLAS; SAMUEL EISMONT; §  
GEORGINA FOULKS; MONICA GARZA; §  
RAY GILPIN; JUDITH GRIMMETT, as §  
Representative of the Estate of JAMES §  
GRIMMETT, Deceased; JUDITH §  
GRIMMETT, Individually, and on behalf of §  
all Wrongful Death Beneficiaries of JAMES §  
GRIMMETT, Deceased, including, but not §  
limited to, JUDITH GRIMMETT; JOY §  
PEREZ, as next friend of ANGELICA §  
PEREZ, minor; STEVEN HIGGS; §  
JEANENE HORN; STEPHEN HOUSE; §  
KAYLA KENDRICK; GLENDETTE §  
KENNEDY, as Representative of the Estate §  
of CHRISTOPHER SUMRALL, Deceased; §  
GLENDETTE KENNEDY, Individually, §  
and on behalf of all Wrongful Death §

Beneficiaries of CHRISTOPHER §  
SUMRALL, Deceased, including, but not §  
limited to GLENDETTE KENNEDY; §  
BERNADETTE LALLY; CASSANDRA §  
LUCCHESI; ANGELA MILLER; §  
BRENDA NEISSER, CARRIE PACK, §  
TRACY PARSONS, BOB RAMBO, as §  
Representative of the Estate of BOBBY §  
JOHN RAMBO, Deceased; BOB RAMBO §  
AND VERONICA RAMBO, Individually, §  
and on behalf of all Wrongful Death §  
Beneficiaries of BOBBY JOHN RAMBO, §  
Deceased, including, but not limited to, BOB §  
RAMBO AND VERONICA RAMBO; §  
MICHAEL RANDOLPH; MICHELLE §  
REINHARDT; RHONDA SMITH; §  
WENDY STEVENS; ALDRIC SUMMERS; §  
AUDREY SULLIVAN; NANCY §  
UPCHURCH; HELEN WHITE, as legal §  
guardian of WALTER NEWBERN; §  
SHAWNITA WILLIAMS; and CAMMIE §  
WILSON, as next friend of CHELSEA RAI §  
SCHALM, minor, §  
*Plaintiffs,* §  
v. §  
MEDTRONIC MINIMED, INC., §  
MEDTRONIC, INC., UNOMEDICAL §  
DEVICES SA DE CV, and UNOMEDICAL §  
A/S, §  
*Defendants.* §

Civil Action No. 7:11-cv-00147

**PLAINTIFFS' AMENDED COMPLAINT**

Plaintiffs, Angela Anderson; Patricia Bailey; Jennifer Balderas; Beonka Bell; Brenda Boston; Kathy Boyd, as next friend of Gage Woolsey, minor; Genie Brazzeal; Debra Canney as representative of the estate of Kevin Bubsey, deceased; Debra Canney, individually, and on behalf of all wrongful death beneficiaries of Kevin Busbey, deceased, including, but not limited to Debra Canney; Tim Costanza, as representative of the estate of Amy Costanza, deceased; Tim Costanza and Janet Costanza, individually, and as wrongful death beneficiaries of Amy

Costanza, deceased; Douglas Dailey; Renee Davis; as representative of the estate of Reynard Craig Bittner, deceased; Renee Davis, individually, and on behalf of all wrongful death beneficiaries of Reynard Craig Bittner, deceased, including, but not limited to, Renee Davis; Roberta Denman; James Douglas; Samuel Eismont; Georgina Foulks; Monica Garza; Ray Gilpin; Judith Grimmett, as representative of the estate of James Grimmett, deceased; Judith Grimmett, individually, and on behalf of all wrongful death beneficiaries of James Grimmett, deceased, including, but not limited to, Judith Grimmett; Steven Higgs; Jeanene Horn; Stephen House; Kayla Kendrick; Glendette Kennedy, as representative of the estate of Christopher Sumrall, deceased; Glendette Kennedy, individually, and on behalf of all wrongful death beneficiaries of Christopher Sumrall, deceased, including, but not limited to, Glendette Kennedy; Bernadette Lally; Cassandra Lucchese; Angela Miller; Brenda Neisser; Carrie Pack; Tracy Parsons; Bob Rambo, as representative of the estate of Bobby John Rambo, deceased; Bob Rambo and Veronica Rambo, individually, and on behalf of all wrongful death beneficiaries of Bobby John Rambo, deceased, including, but not limited to, Bob Rambo and Veronica Rambo; Michael Randolph; Michelle Reinhardt; Rhonda Smith; Wendy Stevens; Aldric Summers; Audrey Sullivan; Nancy Upchurch; Helen White, as guardian of Walter Newbern; Shawnta Williams; and Cammie Wilson, as next friend of Chelsea Rai Schalm, minor, (collectively, "Plaintiffs"), complain of Defendants Medtronic MiniMed, Inc., Medtronic, Inc., Unomedical Devices SA de CV, and Unomedical A/S (collectively, "Defendants" or "Medtronic") as follows:

### **I. DISCOVERY PLAN**

1. Discovery in this case is intended to be conducted under Level 2 pursuant to Rule 190.3 of the Texas Rules of Civil Procedure.

## **II. PARTIES AND SERVICE**

2. Plaintiff Angela Anderson is, and at all times material hereto was, an individual residing in Gainesville, Georgia and a citizen of Georgia.

3. Plaintiff Patricia Bailey is, and at all times material hereto was, an individual residing in Baytown, Texas and is a citizen of Texas.

4. Plaintiff Jennifer Balderas is, and at all times material hereto was, an individual residing in Kennewick, Washington and is a citizen of Washington. Jennifer Balderas only brings suit against Unomedical Devices SA de CV and Unomedical A/S.

5. Beonka Bell is, and at all times material hereto was, an individual residing in Orlando, Florida and is a citizen of Florida.

6. Plaintiff Brenda Boston is, and at all times material hereto was, an individual residing in Rowlett, Texas and is a citizen of Texas.

7. Plaintiff Kathy Boyd, as next friend of Gage Woolsey, minor, is, and at all times material hereto was, an individual residing in Lincoln, Nebraska and is a citizen of Nebraska.

8. Plaintiff Genie Brazzeal is, and at all times material hereto was, an individual residing in Savannah, Georgia and is a citizen of Georgia.

9. Plaintiff Debra Canney as representative of the estate of Kevin Bubsey, deceased; Debra Canney, individually, and on behalf of all wrongful death beneficiaries of Kevin Bubsey, deceased, including, but not limited to Debra Canney, is, and at all times material hereto was, an individual residing in Jupiter, Florida and is a citizen of Florida. Debra Canney, has been or intends to be appointed as representatives of the estate of Kevin Bubsey.

10. Plaintiff Tim Costanza, as representative of the estate of Amy Costanza, deceased; Tim Costanza and Janet Costanza, individually, and as wrongful death beneficiaries of Amy Costanza, deceased, including, but not limited to, Tim Costanza and Janet Costanza, are,

and at all times material hereto were, individuals residing in Boerne, Texas and a citizen of Texas. Tim Costanza has been or intends to be appointed as representatives of the estate of Amy Costanza.

11. Plaintiff Douglas Dailey is, and at all times material hereto was, an individual residing in Georgia and a citizen of Georgia.

12. Plaintiff Renee Davis, as representative of the estate of Reynard Craig Bittner, deceased; Renee Davis, individually, and on behalf of all wrongful death beneficiaries, of Reynard Craig Bittner, deceased, including, but not limited to, Renee Davis is, and at all times material hereto was, an individual residing in Moyock, North Carolina and is a citizen of North Carolina. Renee Davis has been or intends to be appointed as representatives of the estate of Reynard Craig Bittner.

13. Plaintiff Roberta Denman is, and at all times material hereto was, an individual residing in Indianapolis, Indiana and a citizen of Indiana.

14. Plaintiff James Douglas is, and at all times material hereto was, an individual residing in Spring Hill, Florida and is a citizen of Florida.

15. Plaintiff Samuel Eismont is, and at all times material hereto was, an individual residing in Flagstone, Missouri and is a citizen of Missouri.

16. Plaintiff Georgina Foulks is, and at all times material hereto was, an individual residing in Gaston, South Carolina and a citizen of South Carolina.

17. Plaintiff Monica Garza is, and at all times material hereto was, an individual residing in Edinburg, Texas and is a citizen of Texas.

18. Plaintiff Ray Gilpin is, and at all times material hereto was, an individual residing in new Plymouth, Idaho and is a citizen of Idaho.

19. Plaintiff Judith Grimmatt, as representative of the estate of James Grimmatt, deceased; Judith Grimmatt, individually, and on behalf of all wrongful death beneficiaries of James Grimmatt, deceased, including, but not limited to, Judith Grimmatt, and Joy Perez, as next friend of Ana Cecilia Grimmatt, minor, and Angelica Perez, minor, are, and at all times material hereto, were individuals residing in Columbus, Georgia and are citizens of Georgia. Judith Grimmatt has been or intends to be appointed as representatives of the estate of James Grimmatt.

20. Plaintiff Steven Higgs is, and at all times material hereto was, an individual residing in Odessa, Washington and is a citizen of Washington.

21. Plaintiff Jeanene Horn is, and at all times material hereto was, an individual residing in North Wilkesboro, North Carolina and is a citizen of North Carolina.

22. Plaintiff Stephen House is, and at all times material hereto was, an individual residing in Apache Junction, Arizona and is a citizen of Arizona.

23. Plaintiff Kayla Kendrick is, and at all times material hereto was, an individual residing in Prestonsburg, Kentucky and is a citizen of Kentucky.

24. Plaintiff Glendette Kennedy as representative of the estate of Christopher Sumrall, deceased; Glendette Kennedy, individually, and on behalf of all wrongful death beneficiaries of Christopher Sumrall, deceased, including, but not limited to Glendette Kennedy, is, and at all times material hereto was, an individual residing in Kentwood Louisiana and a citizen of Louisiana. Glendette Kennedy, has been or intends to be appointed as representatives of the estate of Christopher Sumrall.

25. Plaintiff Bernadette Lally is, and at all times material hereto was, an individual residing in Allston, Massachusetts and is a citizen of Massachusetts.

26. Plaintiff Cassandra Lucchese is, and at all times material hereto was an individual residing in Palm City, Florida and is a citizen of Florida.

27. Plaintiff Angela Miller is, and at all times material hereto was, an individual residing in Newport, North Carolina and is a citizen of North Carolina.

28. Plaintiff Brenda Neisser is, and at all times material hereto was, an individual residing in Fishersville, Virginia and is a citizen of Virginia.

29. Plaintiff Carrie Pack is, and at all times material hereto was, an individual residing in Maricopa, Arizona and is a citizen of Arizona.

30. Plaintiff Tracy Parsons is, and at all times material hereto was, an individual residing in New Port Richey, Florida and is a citizen of Florida.

31. Plaintiff Bob Rambo is, as representative of the estate of Bobby John Rambo, deceased; Bob Rambo and Veronica Rambo, individually, and on behalf of all wrongful death beneficiaries of Bobby John Rambo, deceased, including, but not limited to, Bob Rambo and Veronica Rambo. At all times material hereto all are individuals residing in Dallastown, Pennsylvania and citizens of Pennsylvania. Bob Rambo has been or intends to be appointed as representatives of the estate of Bobby John Rambo.

32. Plaintiff Michael Randolph is, and at all times material hereto was, an individual residing in Westmont, Illinois and is a citizen of Illinois.

33. Plaintiff Michelle Reinhardt is, and at all times material hereto was an individual residing in Massena, Iowa and is a citizen of Iowa.

34. Plaintiff Rhonda Smith is, and at all times material hereto was, an individual residing in St. Louis, Missouri and a citizen of Missouri.

35. Plaintiff Wendy Stevens is, and at all times material hereto was, an individual residing in Birmingham, Alabama and a citizen of Alabama.

36. Plaintiff Aldric Summers is, and at all times material hereto was, an individual residing in Benton, Arkansas and a citizen of Arkansas.

37. Plaintiff Audrey Sullivan is, and at all times material hereto was, an individual residing in Winthrop, Massachusetts and citizen of Massachusetts.

38. Plaintiff Nancy Upchurch is, and at all times material hereto was, an individual residing in Denver, Colorado and is a citizen of Colorado.

39. Plaintiff Helen White, as legal guardian of, Walter Newbern is, and at all times material hereto was, an individual residing in Humboldt, Tennessee and is a citizen of Tennessee.

40. Plaintiff Shawnta Williams is, and at all times material hereto was, an individual residing in College Park, Georgia and a citizen of Georgia.

41. Plaintiff Cammie Wilson, as next friend of, Chelsea Rai Schalm, minor, is, and at all times material hereto was, an individual residing in Wellsburg, West Virginia and a citizen of West Virginia.

42. Defendant Medtronic MiniMed, Inc. ("Medtronic MiniMed") is a corporation organized under the laws of Delaware, with its principal place of business at 18000 Devonshire Street, Northridge, California 91325. Medtronic MiniMed has been served.

43. Defendant Medtronic, Inc. is a corporation organized under the laws of Minnesota, with its principal place of business at 710 Medtronic Parkway LC 355, Minneapolis, MN 55432. Medtronic, Inc. has been served.



44. Defendant Unomedical Devices SA de CV ("Unomedical Devices") is a corporation organized under the laws of Mexico. Unomedical SA, through its attorney Marc Sheiness, has agreed accept service of process at Mr. Sheiness' office address: 1001 McKinney, Suite 1400, Houston, TX 77002-6323, by certified mail, return receipt requested.

45. Defendant Unomedical A/S ("Unomedical A/S") is a corporation organized under the laws of Denmark. Unomedical A/S, through its attorney Marc Sheiness, has agreed accept service of process at Mr. Sheiness' office address: 1001 McKinney, Suite 1400, Houston, TX 77002-6323, by certified mail, return receipt requested.

### **III. JURISDICTION AND VENUE**

46. This Court has subject matter jurisdiction over this cause because the amount in controversy exceeds the minimum jurisdictional limits of this Court. Additionally, the causes of action and damages detailed below are within the subject matter jurisdiction of this Court.

47. This Court has personal jurisdiction over Defendants because they conduct business in Texas sufficient to meet the minimum constitutional contacts required by law.

48. Venue is proper in this Court pursuant to section 28 U.S.C. § 1391(a)(2) as a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District.

### **IV. STATEMENT OF FACTS APPLICABLE TO ALL COUNTS**

#### **A. MiniMed Paradigm Quick-Set Infusion Sets**

49. Defendants manufactured, marketed and distributed the MiniMed Paradigm Quick-Set Infusion Sets which were advertised to deliver insulin from an insulin pump to a diabetes patient in measured amounts. The MiniMed Paradigm Quick-Set Infusion Sets consist of disposable plastic tubes which transport the insulin from the pump to the patient's body. Plaintiffs had no way of knowing, however, that the MiniMed Paradigm Quick-Set Infusion Sets

that they were required to use were defective in design, manufacture, and marketing, and that, even when used in conformance with Defendants' instructions, the sets were prone to deliver incorrect and life-threatening doses of insulin.

**B. Medtronic: High Ideals, Low Quality**

**1. What Medtronic Claims To Do**

50. Medtronic touts its leadership in the medical device industry: "No other company has 25 years of continuous leadership in diabetes device solutions that improve patients' lives. At Medtronic Diabetes, we are passionate about diabetes care, have a highly trusted brand and a proven track record for advancing solutions." This claim is echoed in part of Medtronic's mission statement in which Medtronic vows to "strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service."

**2. What Medtronic Actually Does - The FDA Recall on the MiniMed Paradigm Quick-Set Infusion Sets**

51. On or about June 29, 2009, the FDA issued a "Class 1" recall of many of Defendants' insulin infusion sets labeled as "Paradigm Quick-Set Infusion Sets" that utilized components manufactured by Unomedical Devices SA de CV and Unomedical A/S. Specifically, the FDA recalled infusion sets with model numbers MMT-396, MMT-397, MMT-398, and MMT-399 (with lot number beginning with "8," for example 8XXXXXX). According to the FDA, the devices had been manufactured and distributed from December 1, 2007 through June 18, 2009. A Class 1 recall is "the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious injury or death." As the FDA noted, "These infusion sets may not allow the insulin pump to vent air pressure properly. This could potentially result in the device delivering too much or too little

insulin and may cause serious injury or death." In the recall, three million of the disposable infusion sets were recalled.

**C. Plaintiffs Were Injured By Their Use Of Defendants' Products**

52. Plaintiffs have been diagnosed as being diabetic and are required to infuse insulin into their body to control their blood sugar.

53. Insulin is a hormone that is required to sustain life. In most people, insulin is naturally produced in the pancreas. A person with diabetes, however, either does not produce insulin in sufficient amounts or does not produce insulin at all.

54. The MiniMed Paradigm Quick-Set Infusion Sets used by Plaintiffs included sets with model numbers MMT-396, MMT-397, MMT-398, and MMT-399 with lot numbers beginning with "8," (referred to as "Lot 8 MiniMed Paradigm Quick-Set Infusion Set").

55. Plaintiffs' doctors prescribed the use of the MiniMed insulin pump, with the MiniMed Paradigm Quick-Set Infusion Sets.

56. Plaintiffs were correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when they failed to receive the correct doses of insulin to manage their diabetic condition. Consequently, Plaintiffs were injured due to the incorrect doses of insulin.

57. As a direct and proximate result of Defendants' acts and omissions each Plaintiff has suffered and will continue to suffer damages as are more fully set out below.

**1. Angela Anderson**

58. In August 2001, Angela Anderson's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

59. Angela Anderson was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when on November 15, 2009 and again on December

13, 2009, she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she was hospitalized and diagnosed with hypoglycemia as a result of improper amounts of insulin.

60. As a direct and proximate result of the Defendants' acts and omissions, Angela Anderson has suffered and will continue to suffer damages as are more fully set out below.

**2. Patricia Bailey**

61. In approximately 2002, Patricia Bailey's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

62. Patricia Bailey was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she was hospitalized numerous times, and eventually had kidney failure and kidney and pancreas transplants resulting from improper amounts of insulin.

63. As a direct and proximate result of the Defendants' acts and omissions, Patricia Bailey and her husband Joe Bailey have suffered and will continue to suffer damages as are more fully set out below.

**3. Jennifer Balderas**

64. In February 2008, Jennifer Balderas' doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

65. Jennifer Balderas was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on April 7, 2008 she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, in 2008 she had multiple hospitalizations from episodes of hypoglycemia, hyperglycemia, seizures, and periods of unconsciousness resulting from improper amounts of insulin.

66. As a direct and proximate result of the Unomedical Devices SA de CV and Unomedical A/S's acts and omissions, Jennifer Balderas has suffered and will continue to suffer damages as are more fully set out below. Jennifer Balderas only asserts claims herein against Unomedical Devices SA de CV and Unomedical A/S.

**4. Beonka Bell**

67. In 2008, Beonka Bell's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

68. Beonka Bell was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, in 2009 she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she was hospitalized four to five times, suffered kidney failure, and her pregnancy was terminated resulting from improper amounts of insulin.

69. As a direct and proximate result of the Defendants' acts and omissions, Beonka Bell has suffered and will continue to suffer damages as are more fully set out below.

**5. Brenda Boston**

70. In 2002, Brenda Boston's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

71. Brenda Boston was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, in 2009, she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she suffered from a transient ischemic attack, was hospitalized at least ten times, suffers from deteriorating eyesight, speech problems, confusion, and anxiety resulting from improper amounts of insulin.

72. As a direct and proximate result of the Defendants' acts and omissions, Brenda Boston has suffered and will continue to suffer damages as are more fully set out below.

**6. Kathy Boyd, as next friend of, Gage Woolsey, minor**

73. In August 2007, Gage Woolsey's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

74. Gage Woolsey was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, in 2009, he had several hospitalizations when he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he suffered hypoglycemia and hyperglycemia resulting from improper amounts of insulin.

75. As a direct and proximate result of the Defendants' acts and omissions, Gage Woolsey has suffered and will continue to suffer damages as are more fully set out below.

**7. Genie Brazzeal**

76. Plaintiff Genie Brazzeal's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

77. Plaintiff Genie Brazzeal was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on July 15, 2009, she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, Plaintiff Genie Brazzeal was hospitalized resulting from improper amounts of insulin.

78. As a direct and proximate result of the acts and omissions of Defendants, Genie Brazzeal has suffered and will continue to suffer damages as are more fully set out below.

**8. Debra Canney as representative of the estate of Kevin Bubsey, deceased; Debra Canney, individually, and on behalf of all wrongful death beneficiaries of Kevin Bubsey, deceased, including, but not limited to Debra Canney**

79. In October 2007, Kevin Bubsey's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

80. Kevin Bubsey was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on November 8, 2008, he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he died from improper amounts of insulin.

81. As a direct and proximate result of the Defendants' acts and omissions, Kevin Bubsey suffered, and Debra Canney has and will continue to suffer, damages as are more fully set out below.

**9. Tim Costanza, as representative of the estate of Amy Costanza, deceased; Tim Costanza and Janet Costanza, individually, and as wrongful death beneficiaries of Amy Costanza, deceased**

82. In 2008, Amy Costanza's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

83. Amy Costanza was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on or about October 7-8, 2008, she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she went into a diabetic coma and died as a result of improper amounts of insulin.

84. As a direct and proximate result of the Defendants' acts and omissions, Amy Costanza has suffered, and Tim and Janet Costanza has and will continue to suffer, damages as are more fully set out below.

**10. Douglas Dailey**

85. Douglas Dailey's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

86. Douglas Dailey was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on February 14, 2009, he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he suffered dizziness

and fainting, and had an automobile accident and was hospitalized resulting from improper amounts of insulin.

87. As a direct and proximate result of the Defendants' acts and omissions, Douglas Dailey has suffered and will continue to suffer damages as are more fully set out below.

**11. Renee Davis, as representative of the estate of Reynard Craig Bittner, deceased; Renee Davis, individually, and on behalf of all wrongful death beneficiaries of Reynard Craig Bittner, deceased, including, but not limited to, Renee Davis**

88. Reynard Craig Bittner's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

89. Reynard Craig Bittner was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on May 31, 2009, he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he died as a result from improper amounts of insulin.

90. As a direct and proximate result of the Defendants' acts and omissions, Reynard Craig Bittner has suffered, and Renee Davis has and will continue to suffer, damages as are more fully set out below.

**12. Roberta Denman**

91. In September 2007, Roberta Denman's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

92. Roberta Denman was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on July 2, 2009, she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she was hospitalized and lapsed into a coma for several days resulting from improper amounts of insulin.



93. As a direct and proximate result of the Defendants' acts and omissions, Roberta Denman has suffered and will continue to suffer damages as are more fully set out below.

**13. James Douglas**

94. James Douglas's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

95. James Douglas was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on November 16, 2009, he failed to receive the correct doses of insulin to manage his diabetic condition and was hospitalized for weeks. On December 14, 2009 he again failed to receive the correct doses of insulin to manage his diabetic condition and had an automobile accident which caused severe injuries to himself and other passengers. These incidents were a result of improper amounts of insulin.

96. As a direct and proximate result of the Defendants' acts and omissions, James Douglas has suffered and will continue to suffer damages as are more fully set out below.

**14. Samuel Eismont**

97. In November 2007, Samuel Eismont's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set infusion set.

98. Samuel Eismont was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when he repeatedly failed to receive the correct dose of insulin to manage his diabetic condition. Consequently, Samuel Eismont was hospitalized at least ten times due to the failure of the pump.

99. As a direct and proximate result of the acts and omissions of Defendants, Samuel Eismont has suffered and will continue to suffer damages as are more fully set out below.

**15. Georgina Foulks**

100. Georgina Foulks' doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

101. Georgina Foulks was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she was hospitalized resulting from improper amounts of insulin.

102. As a direct and proximate result of the Defendants' acts and omissions, Georgina Foulks has suffered and will continue to suffer damages as are more fully set out below.

**16. Monica Garza**

103. In January 2008, Monica Garza's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

104. Monica Garza was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when she repeatedly failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she suffered dizziness, weakness, increased thirst, dry mouth, difficulty speaking, sleepiness, smelly breath, extreme anxiety, hunger, shortness of breath, extreme nausea, fatigue, confusion, extreme irregular heartbeat, hyperglycemia with chest pains and heart palpitations, and in June 2009 she suffered retinal detachment with multiple tears of the left eye, resulting from improper amounts of insulin.

105. As a direct and proximate result of the Defendants' acts and omissions, Monica Garza has suffered and will continue to suffer damages as are more fully set out below.

**17. Ray Gilpin**

106. In 2005, Ray Gilpin's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

107. Ray Gilpin was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he was hospitalized multiple times resulting from improper amounts of insulin.

108. As a direct and proximate result of the Defendants' acts and omissions, Ray Gilpin has suffered and will continue to suffer damages as are more fully set out below.

**18. Judith Grimmatt, as representative of the estate of James Grimmatt, deceased; Judith Grimmatt, individually, and on behalf of all wrongful death beneficiaries of James Grimmatt, deceased, including, but not limited to, Judith Grimmatt; and Joy Perez, as next friend of Ana Cecilia Grimmatt, minor, and Angelica Perez, minor**

109. In 2008, James Grimmatt's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

110. James Grimmatt was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when on numerous occasions he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he lost consciousness while driving and died in a fatal car accident resulting from improper amounts of insulin. His two grandchildren, Ana Cecilia Grimmatt and Angelica Perez, were in the car and also suffered severe injuries resulting from James Grimmatt receiving improper amounts of insulin.

111. As a direct and proximate result of the Defendants' acts and omissions, James Grimmatt has suffered, and Judith Grimmatt, Ana Cecilia Grimmatt, and Angelica Perez have and will continue to suffer, damages as are more fully set out below.

**19. Steven Higgs**

112. In approximately 2008, Steven Higgs' doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

113. Steven Higgs was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he went into diabetic ketoacidosis, had multiple diabetic comas and multiple hospitalizations resulting from improper amounts of insulin.

114. As a direct and proximate result of the Defendants' acts and omissions, Steven Higgs has suffered and will continue to suffer damages as are more fully set out below.

**20. Jeanene Horn**

115. In January 2006, Jeanene Horn's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

116. Jeanene Horn was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on October 21, 2009 and again a few days later, she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she suffered low blood sugar levels which caused her to become dizzy and disoriented including one incident while driving resulting from improper amounts of insulin.

117. As a direct and proximate result of the Defendants' acts and omissions, Jeanene Horn has suffered and will continue to suffer damages as are more fully set out below.

**21. Stephen House**

118. In June 2007, Stephen House's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

119. Stephen House was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, in 2009, he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he developed high blood sugar levels and an infection at the insertion site resulting from improper amounts of insulin and defects in the Lot 8 Medtronic Paradigm Quick-set infusion set.

120. As a direct and proximate result of the Defendants' acts and omissions, Stephen House has suffered and will continue to suffer damages as are more fully set out below.

**22. Kayla Kendrick**

121. In March 2008, Kayla Kendrick's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

122. Kayla Kendrick was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on May 1, 2008, she failed to receive the correct doses of insulin to manage her diabetic condition. The pump and infusion sets continued to fail multiple times throughout 2008 and 2009. Consequently, she suffered numerous debilitating seizures resulting from improper amounts of insulin.

123. As a direct and proximate result of the Defendants' acts and omissions, Kayla Kendrick has suffered and will continue to suffer damages as are more fully set out below.

**23. Glendette Kennedy as representative of the estate of Christopher Summral, deceased; Glendette Kennedy, individually, and on behalf of all wrongful death beneficiaries of Christopher Summral, deceased, including, but not limited to Glendette Kennedy**

124. In August 2008, Christopher Summral's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

125. Christopher Summral was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on August 22, 2009, he failed to receive the correct doses of insulin to manage his diabetic condition and died as a result of improper amounts of insulin.

126. As a direct and proximate result of the Defendants' acts and omissions, Christopher Summral has suffered, and Glendette Kennedy has and will continue to suffer, damages as are more fully set out below.

**24. Bernadette Lally**

127. In or around 2002-2003, Bernadette Lally's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

128. Bernadette Lally was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on October 12, 2008, she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she suffered dizziness, weakness, increased thirst, difficulty speaking, nausea, confusion, and diabetic coma resulting from improper amounts of insulin.

129. As a direct and proximate result of the Defendants' acts and omissions, Bernadette Lally has suffered and will continue to suffer damages as are more fully set out below.

**25. Cassandra Lucchese**

130. In 1998, Cassandra Lucchese's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

131. Cassandra Lucchese was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when on multiple occasions she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she was hospitalized numerous times and involved in a car accident as a result of receiving improper amounts of insulin.

132. As a direct and proximate result of the Defendants' acts and omissions, Cassandra Lucchese has suffered and will continue to suffer damages as are more fully set out below.

**26. Angela Miller**

133. Plaintiff Angela Miller's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set infusion set.

134. Angela Miller was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on June 2, 2009, she failed to receive the correct dose of insulin to manage her diabetic condition. Consequently, Angela Miller was hospitalized due to the failure of the pump.

135. As a direct and proximate result of the acts and omissions of Defendants, Plaintiff Angela Miller has suffered and will continue to suffer damages as are more fully set out below.

**27. Brenda Neisser**

136. In October 2007, Brenda Neiser's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

137. Brenda Neisser was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, in 2008, she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she began having dizziness, fainting, weakness, increased thirst, difficulty speaking, confusion, excessive sweating, nausea, suffered injuries from a fall in May 2008, and an automobile accident in November 14, 2008, all resulting from improper amounts of insulin.

138. As a direct and proximate result of the Defendants' acts and omissions, Brenda Neisser has suffered and will continue to suffer damages as are more fully set out below.

**28. Carrie Pack**

139. In 1999, Plaintiff Carrie Pack's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set infusion set.

140. Carrie Pack was correctly using a Medtronic MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on March 12, 2009 and on March 20, 2009, she failed to receive the correct dose of insulin to manage her diabetic condition. Carrie Pack suffered a near-fatal diabetic crisis which resulted in her hospitalization.

141. As a direct and proximate result of the acts and omissions of Defendants, Carrie Pack has suffered and will continue to suffer damages as are more fully set out below.

**29. Tracy Parsons**

142. In approximately 2002, Tracy Parsons' doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

143. Tracy Parsons was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she was hospitalized resulting from improper amounts of insulin.

144. As a direct and proximate result of the Defendants' acts and omissions, Tracy Parsons has suffered and will continue to suffer damages as are more fully set out below.

**30. Bob Rambo is, as representative of the estate of Bobby John Rambo, deceased; Bob Rambo and Veronica Rambo, individually, and as wrongful death beneficiaries of Bobby John Rambo, deceased**

145. In or around November-December 2006, Bobby John Rambo's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

146. Bobby John Rambo was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on May 23, 2009, he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he died in a single vehicle motorcycle accident resulting from improper amounts of insulin.

147. As a direct and proximate result of the Defendants' acts and omissions, Bobby John Rambo suffered, and Bob Rambo and Veronica Rambo has and will continue to suffer damages as are more fully set out below.



**31. Michael Randolph**

148. In approximately 2002-2003, Michael Randolph's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

149. Michael Randolph was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on multiple occasions in June 2009, he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he was hospitalized numerous times and severely injured resulting from improper amounts of insulin.

150. As a direct and proximate result of the Defendants' acts and omissions, Michael Randolph has suffered and will continue to suffer damages as are more fully set out below.

**32. Michelle Reinhardt on behalf of Michelle Reinhardt**

151. In 2008, Michelle Reinhardt's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

152. Michelle Reinhardt was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she was hospitalized resulting from improper amounts of insulin.

153. As a direct and proximate result of the Defendants' acts and omissions, Michelle Reinhardt has suffered and will continue to suffer damages as are more fully set out below.

**33. Rhonda Smith**

154. In December 2004, Rhonda Smith's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

155. Rhonda Smith was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on January 17, 2009, she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she suffered dizziness,

fainting, weakness, sleepiness, increased thirst, smelly breath, anxiety, shortness of breath, nausea, and irregular heartbeat, resulting from improper amounts of insulin.

156. As a direct and proximate result of the Defendants' acts and omissions, Rhonda Smith has suffered and will continue to suffer damages as are more fully set out below.

**34. Wendy Stevens**

157. In or around June-July 2001, Wendy Stevens' doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

158. Wendy Stevens was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on November 28, 2008, she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she suffered dizziness, fainting, weakness, sleepiness, increased thirst, difficulty speaking, confusion, smelly breath, anxiety, excessive sweating, shortness of breath, nausea, irregular heartbeat, unconsciousness and hospitalization, all resulting from improper amounts of insulin.

159. As a direct and proximate result of the Defendants' acts and omissions, Wendy Stevens has suffered and will continue to suffer damages as are more fully set out below.

**35. Aldric Summers**

160. In 2002, Aldric Summers' doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

161. Aldric Summers was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he was hospitalized resulting from improper amounts of insulin.

162. As a direct and proximate result of the Defendants' acts and omissions, Aldric Summers has suffered and will continue to suffer damages as are more fully set out below.

**36. Audrey Sullivan**

163. In January 2006, Audrey Sullivan's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

164. Audrey Sullivan was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when on multiple occasions she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she was hospitalized numerous times resulting from improper amounts of insulin.

165. As a direct and proximate result of the Defendants' acts and omissions, Audrey Sullivan has suffered and will continue to suffer damages as are more fully set out below.

**37. Nancy Upchurch**

166. In July 2002, Nancy Upchurch's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

167. Nancy Upchurch was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she suffered weakness, increased thirst, sleepiness, difficulty speaking with slurred speech, smelly breath, excessive sweating, nausea, confusion, irregular heart rate, lightheadedness and hospitalization, all resulting from improper amounts of insulin.

168. As a direct and proximate result of the Defendants' acts and omissions, Nancy Upchurch has suffered and will continue to suffer damages as are more fully set out below.

**38. Helen White, as legal guardian of, Walter Newbern**

169. In January 2009, Walter Newbern's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

170. Walter Newbern was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on January 14, 2009, he failed to receive the correct doses of insulin to manage his diabetic condition. Consequently, he suffered dizziness, weakness, increased thirst, fainting, difficulty speaking, sleepiness, anxiety, excessive sweating, shortness of breath, nausea, confusion, irregular heartbeat, and subsequently suffered stroke and heart attack for which he was hospitalized, all of which resulted from improper amounts of insulin.

171. As a direct and proximate result of the Defendants' acts and omissions, Walter Newbern has suffered and will continue to suffer damages as are more fully set out below.

**39. Shawnta Williams**

172. In March 2008, Shawnta Williams' doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

173. Shawnta Williams was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, while she was pregnant, she failed to receive the correct doses of insulin to manage her diabetic condition. Consequently, she was hospitalized and her son died as a result of improper amounts of insulin.

174. As a direct and proximate result of the Defendants' acts and omissions, Shawnta Williams' son has suffered, and Shawnta Williams has suffered and will continue to suffer, damages as are more fully set out below.

**40. Cammie Wilson, as next friend of, Chelsea Rai Schalm, minor**

175. In approximately 2002-2003, Chelsea Rai Schalm's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

176. Chelsea Rai Schalm was correctly using the MiniMed insulin pump with a Lot 8 MiniMed Paradigm Quick-Set Infusion Set when, on May 12, 2009, she failed to receive the

correct doses of insulin to manage her diabetic condition. Consequently, she suffered seizure and hospitalization which resulted from improper amounts of insulin.

177. As a direct and proximate result of the Defendants' acts and omissions, Chelsea Schalm has suffered and will continue to suffer damages as are more fully set out below.

## **V. CAUSES OF ACTION**

### **A. Count One: Strict Liability**

178. Plaintiffs adopt by reference each and every paragraph of the Statements of Facts Applicable to All Counts of the Petition as if fully copied and set forth at length herein.

179. Defendants were the designers, manufacturers, marketers, sellers and/or distributors of various medical instrumentalities, including the MiniMed Paradigm Quick-Set Infusion Sets, for use by ultimate consumers, including Plaintiffs.

180. Plaintiffs purchased the medical instrumentalities and the component parts manufactured by Defendants from distributors of diabetic supplies as well as directly from Defendants. The component parts were in their original packaging which was firmly sealed and in the condition existing at the time of their delivery by Defendants to their distributors and/or to Plaintiffs' physicians or other health care providers or to Plaintiffs individually.

181. Defendants designed, manufactured, marketed, sold, and/or distributed the medical instrumentalities and the component parts thereof used by Plaintiffs in the treatment of their diabetic condition.

182. The Lot 8 MiniMed Paradigm Quick-Set Infusion Sets were defective and unreasonably dangerous, when sold, in that they failed to properly infuse the required dosage of insulin into Plaintiffs' systems.

183. The medical instrumentalities, including the Lot 8 MiniMed Paradigm Quick-Set Infusion Sets, were intended to and did reach Plaintiffs without substantial change in condition from when they left Defendants' control.

184. The faulty design marketing and/or manufacture of the component parts of the devices manufactured, produced and placed into the stream of commerce by Defendants were a producing cause of in the injuries and damages to Plaintiffs as set out herein.

185. The risk that an incorrect dosage of insulin might be delivered was a risk of harm that was inherent in the product, or that might arise from the intended or reasonably anticipated use of the product.

186. Defendants either actually knew, or reasonably should have foreseen, the aforesaid risk of harm at the time it marketed the product.

187. Defendants failed to warn, or to adequately warn, of the aforesaid danger, or failed to give instructions, or adequate instructions, on how to avoid the danger.

188. The product was unreasonably dangerous as marketed because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer with the knowledge common to the community as to its characteristics.

189. The product was the producing cause of Plaintiffs' harm, more particularly described below.

**1. Design Defect**

190. The design of the product rendered it unreasonably dangerous, taking into consideration the utility of the product and the risk involved in its use.

191. There was a safer alternative design other than the one used that in reasonable probability would have prevented or significantly reduced the risk of incorrect doses of insulin

being administered and causing personal physical injury or physical sickness that would not have impaired the products utility; and was economically and technologically feasible at the time the product left Defendants' control by the application of existing or reasonably achievable scientific knowledge.

192. The foregoing defects, more particularly described above, were a producing cause of Plaintiffs' injuries and damages, more particularly described below.

## **2. Manufacturing Defect**

193. The product deviated, in its construction or quality, from its specifications or planned output in a manner that rendered it unreasonably dangerous.

194. The product was unreasonably dangerous as manufactured because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer with the knowledge common to the community as to its characteristics.

195. The foregoing defects, more particularly described above, were a producing cause of Plaintiffs' injuries and damages, more particularly described below.

## **3. Inadequate Instructions or Warnings**

196. The product was defective and unreasonably dangerous due to Defendants' failure of adequate instruction and the failure to warn of the dangers involved in using it.

197. The dangers were foreseeable to the Defendants at the time it marketed the product.

198. The foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the Defendants.

199. The omission of these instructions and warnings rendered the product not reasonably save.

200. The failure to warn, more particularly described above, was a producing cause of Plaintiffs' injuries and damages, more particularly described below.

**B. Count Two: Breach Of Express Warranty**

201. Plaintiffs adopt by reference each and every paragraph of the Statements of Facts Applicable to All Counts as if fully copied and set forth at length herein.

202. At all times material hereto Defendants expressly represented and warranted to both healthcare providers and to the ultimate consumers of its products, including Plaintiffs, that the MiniMed Paradigm Quick-Set Infusion Sets would safely and efficiently deliver the required measured dose of insulin into the consumers' system to prevent blood sugar imbalance and the consequences thereof.

203. Prior to the purchase of the medical instrumentalities and the component parts thereof by Plaintiffs as alleged above, Defendants induced Plaintiffs' purchase of said instrumentalities by expressly warranting or representing directly to Plaintiffs, as well as to their physician and/or other health care providers, that the instrumentalities and the component parts thereof would safely and efficiently deliver the required dosage of insulin at the specific times required.

204. In purchasing the instrumentalities and their component parts, Plaintiffs relied on the skill and judgment of Defendants and on Defendants' express warranties and representations as described above. Such warranties and representations formed a part of the basis of the bargain in which Plaintiffs selected and purchased the MiniMed Paradigm Quick-Set Infusion Sets.

205. Defendants breached the express warranty by designing, manufacturing and marketing a defective product that, in fact, failed to deliver the prescribed measured dosage of insulin at the specific time required.



206. Defendants' breach of express warranties proximately and directly caused Plaintiffs' injuries and damages as set out herein.

**C. Count Three: Breach Of Implied Warranty Of Fitness For A Particular Purpose**

207. Plaintiffs adopt by reference each and every paragraph of the Statements of Facts Applicable to All Counts of the Petition as if fully copied and set forth at length herein.

208. Defendants knew or should have known the particular purpose for which Plaintiffs purchased the medical instrumentality and its component parts because the purpose for which Defendants sold these particular medical devices was solely for the infusion of insulin into the ultimate consumers' system to control his or her diabetic condition.

209. Defendants impliedly warranted that the MiniMed insulin pump and its component parts including the MiniMed Paradigm Quick-Set Infusion Sets were fit for the purpose for which they were designed and manufactured and that they were, in fact, suitable for the use made by Plaintiffs.

210. In purchasing and using the medical devices described herein, Plaintiffs relied on Defendants' skill and judgment and the implied warranty of fitness for a particular purpose for which Plaintiffs purchased the insulin pump and its component parts.

211. The MiniMed Paradigm Quick-Set Infusion Sets were not fit for use for their intended purpose because they had a tendency to cause the infusion of an incorrect dose of insulin into the system of Plaintiffs.

212. Defendants' breach of the implied warranty of fitness for a particular purpose directly and proximately caused Plaintiffs' injuries and damages more fully set out below.

**D. Count Four: Breach Of Implied Warranty Of Merchantability**

213. Plaintiffs adopt by reference each and every paragraph of the Statements of Facts Applicable to All Counts of the Petition as if fully copied and set forth at length herein.

214. Defendants impliedly warranted that the medical instrumentalities and the component parts thereof were of a merchantable quality, fit, safe and in proper condition for the ordinary use for which such devices are designed, manufactured, marketed and used.

215. In purchasing and using the instrumentalities designed, produced and marketed by Defendants, Plaintiffs relied on Defendants' skill and judgment, and the implied warranty of merchantability for the purpose for which Plaintiffs purchased said instrumentalities.

216. The medical devices and instrumentalities and the component parts thereof purchased by Plaintiffs were not merchantable in that among other things, either in conjunction or separately, they had the tendency to fail to introduce the required regular measured dosage of insulin into Plaintiffs' body. For this reason, the product was unfit for ordinary purposes. The product was unfit for ordinary purposes because it was unreasonably dangerous.

217. Defendants' breach of the implied warranty of merchantability as is particularly set forth herein directly and proximately resulted in Plaintiffs' injuries and damages as set out below.

**E. Count Five: Negligence**

218. Plaintiffs adopt by reference each and every paragraph of the Statements of Facts Applicable to All Counts of the Petition as if fully copied and set forth at length herein.

219. At all times material hereto Defendants were engaged in the manufacture of medical devices and instrumentalities used to infuse measured doses of insulin into the systems of patients with diabetic conditions. These devices and instrumentalities were marketed and sold to various physicians and other health care providers and directly to the ultimate consumers, including Plaintiffs.

220. Defendants owed to Plaintiffs and the public a duty to use reasonable care in the testing and inspecting of their medical instrumentalities and devices, in designing the devices and

the component parts thereof and in manufacturing and marketing those medical devices, including the MiniMed Paradigm Quick-Set Infusion Sets.

221. Defendants breached this duty by being negligent in their design, manufacture, and marketing of the MiniMed Paradigm Quick-Set Infusion Sets in one or more of the following particulars, among others:

- (a) In designing MiniMed Paradigm Quick-Set Infusion Sets in a manner which caused them to fail to vent properly resulting in an incorrect dosage of insulin into the system of patients including Plaintiffs.
- (b) In failing to adequately test the MiniMed Paradigm Quick-Set Infusion Sets.
- (c) In failing to properly market the MiniMed Paradigm Quick-Set Infusion Sets.
- (d) In failing to provide adequate warnings, information about the risks and hazards of the MiniMed Paradigm Quick-Set Infusion Sets.
- (e) In failing to provide proper instructions to enable consumers to accurately use the MiniMed Paradigm Quick-Set Infusion Sets.
- (f) In delivering the MiniMed Paradigm Quick-Set Infusion Sets directly to consumers without sufficient personal training on the instructions for using the device.
- (g) In failing to accurately manufacture the MiniMed Paradigm Quick-Set Infusion Sets.

222. The design, manufacture, marketing, and function of the MiniMed Paradigm Quick-Set Infusion Sets were within Defendants' exclusive control.

223. The specific facts concerning the design, manufacture, marketing, and function of the MiniMed Paradigm Quick-Set Infusion Sets are particularly within the knowledge of Defendants, and Plaintiffs have no means of ascertaining the method or manner in which the pump and its component parts were designed, manufactured or marketed.

224. The MiniMed Paradigm Quick-Set Infusion Sets designed, produced and marketed by Defendants came into Plaintiffs' possession in the same condition as they were in when they left the control of Defendants.

225. The occurrences that caused harm to Plaintiffs, as described above, were ones which in the ordinary course of events would not have occurred without negligence on the parts of Defendants. For these reasons, the doctrine of *res ipsa loquitur* permits a finder of fact to infer negligence on the part of Defendants.

226. As a direct and proximate result of the acts and omissions of Defendants, whether taken singularly or in any combination, Plaintiffs suffered injuries and damages as more fully set forth below.

## **VI. PUNITIVE DAMAGES**

227. Plaintiffs adopt by reference each and every foregoing paragraph as if fully copied and set forth at length herein.

228. Defendants' conduct, when viewed objectively from Defendants' standpoints at the time of its occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to diabetics, including Plaintiffs.

229. Further, Defendants had actual, subjective awareness of the risk involved with respect to their conduct, but nevertheless proceeded with conscious indifference to the rights, safety and welfare of others. Defendants knew that there was a high probability that inaccurate doses of insulin could occur and would result in serious injury.

230. Defendants are liable for punitive damages in respondeat superior for the conduct of their agents, representatives or employees that engaged in the above conduct to one or more of the following reasons:

- (a) Defendants authorized the doing and manner of such conduct;

- (b) one or more of such agents, representatives or employees were unfit, and Defendants were reckless in employing him or her;
- (c) one or more of such agents, representatives or employees were employed by Defendants in a managerial capacity and acting within the scope of such and acting within the scope of such agency or employment;
- (d) Defendants or a manager of Defendants ratified or approved the conduct of such agents, representatives or employees.

#### **VII. DAMAGES APPLICABLE TO ALL COUNTS**

231. Plaintiffs adopt by reference each and every foregoing paragraph as if fully copied and set forth at length herein.

232. As a producing and proximate result of Defendants' products and Defendants' conduct as described above, Plaintiffs suffered in the past, and in reasonable medical probability will continue to suffer in the future the following injuries and damages:

- (a) physical pain, past and future;
- (b) mental anguish, past and future;
- (c) physical impairment, past and future;
- (d) reasonable and necessary medical expenses, past and future;
- (e) loss of earnings, earnings capacity, or both, past and future;
- (f) loss of the enjoyment of life, past and future; and,
- (h) other incidental damage(s).

#### **VIII. CONDITIONS PRECEDENT**

233. All conditions precedent have been performed or have occurred.

#### **IX. JURY DEMAND**

234. Plaintiffs hereby request a trial by jury.

**X. PRAYER**

WHEREFORE Plaintiffs prays that Defendants be cited to appear and answer herein and that, upon final trial, Plaintiffs be awarded judgment against Defendants jointly and severally:

- (a) for compensatory damages;
- (b) for punitive damages;
- (c) prejudgment interest;
- (d) post-judgment interest;
- (e) costs of Court; and
- (f) such other and further relief to which Plaintiffs show that they are justly entitled to receive.

Respectfully submitted,

By: /s/Neeley G. Morgan

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**CERTIFICATE OF SERVICE**

I hereby certify that I served the above captioned document on opposing counsel by certified mail on the 5<sup>th</sup> day of April, 2012 as listed below.

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